## REMARKS

Claims 1-25 are currently pending in this application. Claim 19 stands withdrawn. Claims 1-3, 7, 10-18 and 20-25 are amended herein. Support for the claim amendments can be found throughout the application as originally filed, *inter alia*, on page 14, paragraph [046]. Accordingly, Applicants submit that no new matter is introduced into the application by way of the instant amendments. Upon entry and consideration of these amendments and remarks, claims 1-25 will remain pending.

In response to the Office Action, Applicants provide the following remarks.

### Rejection Under 35 U.S.C. 102

Claims 2-4, 9 and 25 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Rubin (U.S. Patent No. 5,034,415). (*See* Office Action at page 3.) The Office Action asserts that Rubin teaches that EPA and DHA mixtures are useful for treating diabetes mellitus, and that compositions comprising DHA and EPA can replace butter and/or ordinary margarine or cooking oil.

Applicants respectfully traverse this rejection.

In order for a reference to anticipate under 35 U.S.C. § 102(b), the reference must disclose all elements of the claimed invention. The claimed invention is directed to a method for improving glucose control as measured by glycosylated hemoglobin (HbA1c) from a patient comprising administering DHA to a patient on a periodic basis in an amount sufficient to reduce glycosylation levels of circulating hemoglobin in the patient, wherein the DHA is in a triglyceride oil. Applicants submit that Rubin addresses free fatty acids derived from marine animal oil, linseed oil, and soybean oil. As stated in the Office Action on page 5, line 1, Rubin does not teach glycosylated hemoglobin (HbA1c) measurement in blood. Applicants submit that Rubin does not teach each and every element of the invention as claimed, and therefore does not anticipate the claimed invention.

For the reasons set forth above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 2-4, 9 and 25 under 35 U.S.C. § 102(b) as allegedly anticipated by Rubin.

**Rejections Under 35 U.S.C. 103**

*A. Rubin in view of Remmereit et al.*

Claims 1, 5-8 and 20-24 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rubin in view of Remmereit et al. (U.S. Patent 6,440,931 B1). (*See* Office Action at page 4). The Office Action asserts that it would have been obvious to the skilled artisan to measure the blood glucose level in diabetic patients of Rubin by measuring glycosylated hemoglobin (HbA1c) decrease because Rubin teaches that DHA composition is effective for treating diabetes and because Remmereit et al. teach HbA1c is elevated in patients with poorly managed diabetes, and the determination of HbA1c levels is well known in the art in view of Remmereit et al. (*See* Office Action at page 5.) The Office Action further asserts that one would have been motivated to measured a decrease in HbA1c in diabetic patients disclosed by Rubin in order to determine if the dosing adjustment of DHA/EPA composition in antidiabetic therapy is necessary.

The Office Action further asserts that it would have been obvious to combine other antidiabetic agents such as biguanidines (e.g. metformin), sulphonylurea compounds such as tolbutamide, chlorpropamide, glipizide, and glibenclamide, and acarbose with Rubin's composition in order to achieve at least an additive antidiabetic effect. (*See* Office Action at page 6.) According to the Office Action, the motivation for combining the components flows from their individually known common utility.

Applicants respectfully disagree and traverse this rejection.

Applicants submit that Rubin, considered alone or in combination with Remmereit, neither teaches nor suggests the claimed invention. Even if, as the Office Action asserts, the skilled artisan would have been motivated to employ Rubin's composition to treat diabetes chronically because diabetes mellitus is a chronic disorder in view of Remmereit, this would not

have resulted in the presently claimed invention, because Rubin does not at least teach or suggest the invention as presently claimed. Rubin's deficiencies are presented above under the rejection under 35 U.S.C. § 102. Remmereit does not remedy these deficiencies. Therefore, the claimed invention is not rendered obvious.

Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-8 and 20-24 under 35 U.S.C. 103(a).

*B. Rubin in view of Remmereit et al.*

Claims 10-18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rubin in view of Remmereit et al, as applied to claims 1, 5-8 and 20-24 above, and further in view of Harris et al. While acknowledging that Rubin and Remmereit et al., do not teach the specific patient population recited in claims 10-16 and dosing schedule set forth in claims 17-18, the Office Action asserts that Harris teaches comparison of diabetes diagnostic categories in the U.S. population include impaired fasting glucose defined as fasting plasma glucose of 110-125 mg/dl and mean HbAc1 of 7.07.

The Office Action concludes that it would have been obvious to one of ordinary skill in the art to employ the DHA/EPA composition taught by Rubin as modified by Remmereit et al. to a patient exhibiting fasting glucose between about 110 to about 125 mg/dl and the criteria recited in claims 10-18, *because* a fasting plasma glucose of 110-125 mg/dl is defined as an impaired fasting glucose within the diagnostic classes taught by Harris et al. and because the variations within any one or more of the risk factors would be reasonably expected to differ between patients. The Office Action asserts that the dosing schedule, frequency of administration of the antidiabetic to be used, the pharmaceutical forms, mode of administration, flavors, and surfactants would have been obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration.

Applicants respectfully disagree and traverse this rejection.

The deficiencies of Rubin and Remmereitt have been addressed above in connection with the rejection of claims 1, 5-8, and 20-24, and are repeated and incorporated by reference herein, as applied to the current rejection of claims 10-18. The references, considered individually or in combination, fail to teach or suggest the claimed invention, which relates to the use of DHA in a triglyceride oil. Applicants submit that the deficiencies of the primary reference is not remedied by Harris' general technical teachings, and the combination of references would not have lead to the invention as presently claimed.

For the reasons set forth above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10-18 under 35 U.S.C. 103(a).

## CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

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